UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,956	03/24/2005	C. Mauli Agrawal	5660-00503	8795

35690 7590 04/07/2008

MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.
P.O. BOX 398
AUSTIN, TX 78767-0398

EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
04/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,956	AGRAWAL ET AL.	
	Examiner	Art Unit	
	David M. Naff	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,29-32,63 and 128* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27,29-32,63 and 128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/2/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 1/2/08 amended the specification and claims 1, 32, 63 and 128, and canceled claim 28.

Claims examined on the merits are 1-27, 29-32, 63 and 128, which are all claims in the application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19, 21, 23, 25, 27, 29, 30, 32, 63 and 128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al

(4,927,676) in view of Mineau-Hanschke (6,582,391), and Mineau-Hanschke (6,419,920).

The claims are drawn to method of preparing an implant by subjecting a substrate to gas-plasma treatment and exposing the treated substrate to living cells so a portion of the cells become coupled to the substrate, and produce more of a product than cells coupled to an untreated substrate, and the cells produce vascular endothelial growth factor (VEGF) as the product.

Williams et al disclose attaching endothelial cells to a substrate by treating the substrate with a gas-plasma before attaching the cells (col 2, under "SUMMARY OF THE INVENTION", and col 4, lines 48-59).) The substrate with the attached cells is implanted.

Mineau-Hanschke ('391) discloses providing a medically useful polypeptide to a patient by providing a matrix containing cells that secrete the polypeptide and implanting the matrix (col 4, lines 17-31). The cells in the matrix can be implanted to produce a wide range of cellular products including various growth factors (col 18, lines 31-55).

Mineau-Hanschke ('920) discloses vascular endothelial growth factor as a cellular product (col 4, lines 41-42).

Hoffman et al ('265) disclose using gas-plasma treatment to improve compatibility of biomaterials.

Lee et al disclose surface modification of medical implants by gas-plasma treatement.

Hoffman et al ('316) disclose gas-plasma treatment of a surface to provide tight binding of proteins to the surface.

It would have been obvious to use as cells attached to the substrate to be implanted of Williams et al, cells that produce a cellular product when implanted disclosed by Mineau-Hanschke ('391) to obtain the benefit of cells producing a product *in vivo* as disclosed by Mineau-Hanschke ('391). It would have been obvious to use cells that produce vascular endothelial growth factor as the product as suggested by Mineau-Hanschke ('920) to obtain the known function of vascular endothelial growth factor. Hoffman et al ('265 and '316) and Lee et al further disclose gas-plasma treatment of a substrate, and if needed would have suggested conditions that can be used. Cells attached to the plasma treated substrate will inherently produce more product than cells attached to an untreated substrate. The conditions of dependent claims would have been obvious from conditions disclosed by the references.

Claim Rejections - 35 USC § 103

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-19, 21, 23, 25, 27, 29, 30, 32, 63 and 128 above, and further in view of Berlowitz-Tarrant et al (5,840,387).

The claim requires human aortic endothelial cells.

Berlowitz-Tarrant et al disclose attaching aortic endothelial cells to a surface that can be an implant (col 5, lines 40-65).

When using cells that produce vascular endothelial growth factor as the cells of Williams et al as set forth above, it would have been obvious to use aortic endothelial cells as the cells as suggested by Berlowitz-Tarrant et al disclosing attaching aortic endothelial cells to a surface for implanting.

Claim Rejections - 35 USC § 103

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-19, 21, 23, 25, 27, 29, 30, 32, 63 and 128 above, and further in view of Smith et al (5,580,779).

The claim requires myocardial cells.

Smith et al disclose using myocardial cells to produce a peptide *in vivo* (col 5, lines 3-8).

When using cells that produce vascular endothelial growth factor as the cells of Williams et al as set forth above, it would have been obvious to use myocardial cells to produce a peptide as suggested by Smith et al.

Claim Rejections - 35 USC § 103

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-19, 21, 23, 25, 27, 29, 30, 32, 63 and 128 above, and further in view of Zonneveld et al (6,447,768).

The claim requires the cellular product to be a nucleic acid.

Zonneveld et al disclose delivering a nucleic acid *in vivo* with a cell that produces the nucleic acid to provide gene therapy (abstract and paragraph bridging cols 3 and 4.

When using cells that produce vascular endothelial growth factor as the cells of Williams et al as set forth above, it would have been obvious to use cells that produce a nucleic acid to provide gene therapy as suggested by Zonneveld et al.

Claim Rejections - 35 USC § 103

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-19, 21, 23, 25, 27, 29, 30, 32, 63 and 128 above, and further in view of Beckmann et al (6,306,615).

The claim requires the cellular product to be beta-tubulin.

Beckmann et al disclose beta-tubulin-producing cells (col 16, lines 15-19).

When using cells that produce vascular endothelial growth factor as the cells of Williams et al as set forth above, it would have been obvious to use cells that produce beta-tubulin to obtain its function as suggested by Beckmann et al.

Claim Rejections - 35 USC § 103

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-19, 21, 23, 25, 27, 29, 30, 32, 63 and 128 above, and further in view of Newman et al (6,087,331).

The claim requires platelet-endothelial cell adhesion molecule-1 as a cellular product.

Newman et al disclose therapeutic use of platelet-endothelial cell adhesion molecule-1 and cells transformed to produce platelet-endothelial cell adhesion molecule-1.

When using cells that produce vascular endothelial growth factor as the cells of Williams et al as set forth above, it would have been obvious to use cells that produce platelet-endothelial cell adhesion molecule-1 as suggested by Newman et al.

Response to Arguments

The amendment urges that the claims have been amended to require the cells to produce vascular endothelial growth factor. However, for reasons set forth above, Mineau-Hanschke ('920) would have suggested cells that produce vascular endothelial growth factor. The present claims require the cells to produce vascular endothelial growth factor for the known function of the growth factor, and no unexpected result is seen in using cells that produce a known growth factor to obtain the well known function of the growth factor.

The amendment urges that Mineau-Hanschke ('920) uses vascular endothelial growth factor as an exogenous agent. However, it would have been expected that cells can produce vascular endothelial growth factor from Mineau-Hanschke ('391) disclosing cells producing a wide range of cellular products including various growth factors (col 18, lines 31-55) such as endothelial cell growth factor (col 18, line 41).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date

of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

DMN
3/31/08